

MR-1 REPORT CHECK OFF LISTCompany : **Amneal Pharmaceuticals Corp.**

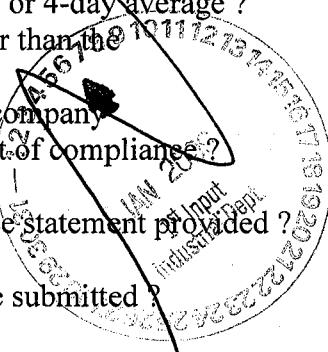
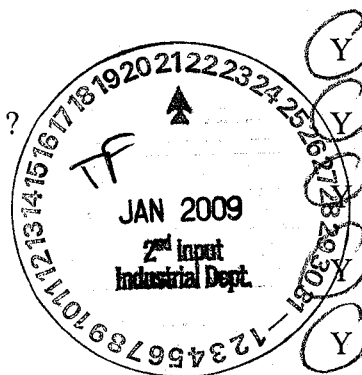
SCP #: 27200050-1

Address : 290 McClean Blvd., Paterson, NJ 07504

Contact : Jiten Parikh

973-357-0222

- | | | | | |
|-----|---|---|---|-------|
| 1. | Category 40 CFR 439.47 (b) Subcategory | D | | |
| 2. | MONTH OF NOVEMBER 1, 2008 THRU NOVEMBER 30, 2008 | | | |
| 3. | Is Outlet # (8 digit) Correct ? | | Y | N N/A |
| 4. | Is regulated flow stated in space provided ? | | Y | N N/A |
| 5. | Total flow provided in proper space ? | | Y | N N/A |
| 6. | Is method used to calculate water stated,? | | Y | N N/A |
| 7. | Are number of working days stated ? | | Y | N N/A |
| 8. | Are there any parameters which have exceeded a daily maximum limit or could cause the company to be out of compliance with a monthly or 4-day average ? | Y | N | N/A |
| 8a | Are any non-detectable results higher than the permits limits ? | Y | N | N/A |
| 8b | If the answer to 8a was yes. did the company submit any documentation in support of compliance ? | Y | N | N/A |
| 9. | Is proper compliance/non-compliance statement provided ? | Y | N | N/A |
| 10. | If applicable is compliance schedule submitted ? | Y | N | N/A |
| 11. | Is combined waste stream formula required ? | Y | N | N/A |
| 12. | If combined waste stream formula was used, have calculations been submitted correctly ? | Y | N | N/A |
| 13. | Have correct number of samples been submitted ? | Y | N | N/A |
| 14. | Has sample number been reported in space provided ? | Y | N | N/A |
| 15. | Have all regulated parameters been listed on MR-1 ? | Y | N | N/A |
| 16. | Has sample type been stated on MR-1 ? | Y | N | N/A |
| 17. | Have all samples been taken during this reporting period ? | Y | N | N/A |
| 18. | Has NJDEPE certified lab been used ? | Y | N | N/A |
| 19. | Have analytical results been submitted on copies of Laboratory stationery ? | Y | N | N/A |



- | | | | | |
|------|--|------------------------------------|------------------------------------|--------------------------------------|
| 20. | Have results been written in space designated on MR-1? | <input checked="" type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> N/A |
| 21. | Have average permit limitations been included on MR-1? | <input checked="" type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> N/A |
| 22. | Have maximum permit limitations been included on MR-1? | <input type="radio"/> Y | <input type="radio"/> N | <input checked="" type="radio"/> N/A |
| 23. | Is method used to preserve samples stated on MR-1? | <input checked="" type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> N/A |
| 24. | If non-use statement is made does regulations allow exemptions ? | <input type="radio"/> Y | <input checked="" type="radio"/> N | <input type="radio"/> N/A |
| 25. | Has updated flow diagram been provided ? | <input type="radio"/> Y | <input checked="" type="radio"/> N | <input type="radio"/> N/A |
| 26. | If the answer to 25 was yes, was the change to the previous plot plan noted ? | <input type="radio"/> Y | <input type="radio"/> N | <input checked="" type="radio"/> N/A |
| 27.. | If the answer to 25 was no or N/A, was the appropriate statement of no-change to diagram submitted ? | <input checked="" type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> N/A |
| 28. | Has production rate been provided if production Based Standards were used ? | <input type="radio"/> Y | <input type="radio"/> N | <input checked="" type="radio"/> N/A |
| 29. | Has MR-1 been signed by authorized representative ? | <input checked="" type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> N/A |
| 29. | Has information been submitted on proper MR-1 form ? | <input checked="" type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> N/A |
| 29. | Have any and all PVSC samples taken during this month been averaged in with the company samples ? | <input type="radio"/> Y | <input type="radio"/> N | <input checked="" type="radio"/> N/A |

First Reviewer: comments on deficiencies COMPLETE

Date Reviewed 1/21/09 Date sent to user _____

Date due back _____ Reviewer C.J.M.

Second Review comments on deficiencies _____

Date Reviewed _____ Date sent to user _____

Date due back _____ Reviewer _____

Date ok _____ Reviewer _____

11/01/08 THRU 11/30/08

AMNEAL PHARMACEUTICALS

(439)

PATERSON

Local Limits

Parameters	Threshold Value	Local Limit	Over Limit	Additional Tests
Cadmium	0.005	0.19	Certified Non-Use	None
Copper	0.092	3.02		Three Months
Lead	0.029	0.54		
Nickel	0.02	5.9	Certified Non-Use	None
Zinc	1.67	1.67		
Mercury	0.001	0.080		Three Months

Violations: noneCOMPLETE ☒ Yes ☐ NoDate 1/21/09

PRETREATMENT MONITORING REPORT

DEC 18 2008

NAME: AMNEAL PHARMACEUTICALS CORPORATION

MAILING ADDRESS: 209 MC LEAN BLVD., PATERSON, NJ 07504

FACILITY LOCATION: 209 MC LEAN BLVD., PATERSON, NJ 07504

CATEGORY & SUBPART: 439 OUTLET #: 1

CONTACT OFFICIAL: JITEN PARIKH TELEPHONE: 973 357-0222

NEW CUSTOMER ID / OUTLET ID: 272-000SD-1 OLD OUTLET DESIGNATION: _____

MONITORING PERIOD		
Start		
11	01	08
MO	DAY	YR

End		
11	30	08
MO	DAY	YR

Average Maximum

Regulated Flow-gal/day 1825 2008

Total Flow-gal/day 3583 3941

Method Used: _____ Flowmeter readings / _____ working days.

PLEASE SEE ATTACHMENT

Production Rate (if applicable) 11

PARAMETER		MASS OR CONCENTRATION			# OF SAMPLES	SAMPLE TYPE COMP/GRAB
		MON AVG	MAXIMUM	UNITS		
Cd	Sample Measurement			Mg/l	1	Comp
	Permit Requirement	0.19		Mg/l		
Cu <u>COPPER</u>	Sample Measurement	<u>0.390</u> ✓		Mg/l	1	Comp
	Permit Requirement	3.02		Mg/l		
Pb <u>LEAD</u>	Sample Measurement	<u>0.0136</u>		Mg/l	1	Comp
	Permit Requirement	0.54		Mg/l		
Hg	Sample Measurement			Mg/l	1	Comp
	Permit Requirement	0.080		Mg/l		
Ni	Sample Measurement			Mg/l	1	Comp
	Permit Requirement	5.9		Mg/l		
Zn <u>ZINC</u>	Sample Measurement	<u>0.145</u> ✓		Mg/l	1	Comp
	Permit Requirement	1.67		Mg/l		
<u>ACETONE</u>	Sample Measurement	<u>0.154</u> ✓		Mg/l	1	Grab
	Permit Requirement	8.2		Mg/l		
<u>METHYLENE CHLORIDE</u>	Sample Measurement	<u>0.0017</u>		Mg/l	1	Grab
	Permit Requirement	0.7		Mg/l		
	Sample Measurement					
	Permit Requirement					
	Sample Measurement					
	Permit Requirement					
	Sample Measurement					
	Permit Requirement					
	Sample Measurement					
	Permit Requirement					
	Sample Measurement					
	Permit Requirement					
	Sample Measurement					
	Permit Requirement					

PRETREATMENT MONITORING REPORT

Certification of Non-Use if applicable (use additional sheets):

N/A

DEC 18 2008

Compliance or non compliance statement with compliance schedule (use additional sheets if necessary) for every

parameter used:

AMNEAL IS IN COMPLIANCE WITH PVSC LOCAL
LIMITS AS WELL AS ALL 40 CFR 439 PARAMETERS

Explain Method for preserving samples:

NITRIC ACID TO A PH LESS THAN 2

I certify under penalty of law that this document and attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

403.6(a)(2)(ii) revised by 53 FR 40610, October 17, 1988

Senen Roxas

Signature of Principal

Executive or Authorized Agent

for: JITEN PARIKH
VICE PRESIDENT

Type Name and Title

12-17-08

Date



METHOD USED

TOTAL WATER USED

$7,403.4 (11/30/08) - 7,307.6 (11/1/08) = 96 \text{ CF1} \times 7.48 \times 100 = 71,658/20 \text{ DAYS} = 3,583 \text{ Total Flow - Gal/Day.}$

SANITARY USED

$1,661 (11/30/08) - 1,614 (11/1/08) = 47 \times 7.48 \times 100 = 35,156/20 \text{ DAYS} = 1,758 \text{ Flow - Gal/Day.}$

$$\text{REGULATORY/TOTAL} = 1,825/3,583 = 0.5$$

SITE PLAN: NO CHANGE

Ms. Sonal Thakar
Amneal Pharmaceutical Corp..
209 McLean Blvd
Paterson, NJ 07054

ANALYSIS REPORT

REPORT DATE: NOV. 18, 2008

PROJECT NO : 813843

LAB ID NO: 813843.1

FIELD ID NO: AP-1111

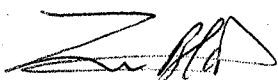
Sample: Liquid, Sampled by CALI on 11/11/08

Analysis	Method Number	Results (mg/L)	Discharge Limitation (mg/L)	RLs (mg/L)	Analysis Date Time	DF
COPPER	200.7	0.390	3.02	0.003	11/13/08 11:09	1
LEAD	200.7	0.0136	0.54	0.005	11/13/08 11:09	1
ZINC	200.7	0.145	1.67	0.005	11/13/08 11:09	1

Definitions:

pH Unit, J= Compound Detected but Below MDL, RLs= Laboratory Reporting Limits,
MDL= Method Detection Limit, DF= Dilution Factor, ND = Not Detected, RL = MDL x DF
All metals analyses performed were subcontracted to NJ certified lab # PA 166

Submitted By:



Zvi Blank, Ph.D., CHMM
Laboratory Director



Ms. Sonal Thakar
Amneal Pharmaceutical Corp..
209 McLean Blvd
Paterson, NJ 07054

ANALYSIS REPORT

REPORT DATE: NOV.18, 2008

PROJECT NO : 813843

LAB ID NO: 813843.2

FIELD ID NO: AP-1111 G

Sample: Liquid, Sampled by CALI on 11/11/08

Analysis	Method Number	Results (µg/L)	Discharge Limitation (mg/L)	RLs (µg/L)	Analysis Date	DF
ACETONE	EPA Method 624	154	8.2	1.76	11/15/08	1
METHYLENE CHLORIDE	EPA Method 624	1.70	0.7	0.69	11/15/08	1

Definitions:

pH Unit, J= Compound Detected but Below MDL, RLs= Laboratory Reporting Limits,

MDL= Method Detection Limit, DF= Dilution Factor, ND = Not Detected, RL = MDL x DF

Analyses performed were subcontracted to NJ certified lab # 07010

Submitted By:



Zvi Blank, Ph.D., CHMM
Laboratory Director





QC Laboratories

Analytical Report



Regarding:

MS. HAYA BLANK
COMPLETE ANALYSIS LABORATORIES, INC.
1259 ROUTE 46
BUILDING #4/C
PARSIPPANY, NJ 07054-4909

MS. HAYA BLANK
COMPLETE ANALYSIS LABORATORIES, INC.
1259 ROUTE 46
BUILDING #4/C
PARSIPPANY, NJ 07054-4909

Account No: W05307, COMPLETE ANALYSIS 1 WK TAT PHILLY QA
Project No: W05307, COMPLETE ANALYSIS 1 WK TAT PHILLY QA

P.O. No:
PWSID No:

Inv. No:

Sample Number	Sample Description	Samp. Date/Time/Temp	Sampled by
L2826820-1	813843.1 COMPOSITE Received Temp: 37 F Iced (Y/N): Y	11/11/08 11:31am NA F	Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
COPPER	EPA 200.7	0.390 mg/l	0.00300 mg/l	11/13/08 11:09AM B B
LEAD	EPA 200.7	0.0136 mg/l	0.00500 mg/l	11/13/08 11:09AM B B
ZINC	EPA 200.7	0.145 mg/l	0.00500 mg/l	11/13/08 11:09AM B B

Sample Number	Sample Description	Samp. Date/Time/Temp	Sampled by
L2826820-2	813843.2 GRAB Received Temp: 37 F Iced (Y/N): Y	11/11/08 11:32am NA F	Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
CHLOROMETHANE	EPA 624	ND ug/l	0.620 ug/l	11/15/08 05:54AM EEW
VINYL CHLORIDE	EPA 624	ND ug/l	0.650 ug/l	11/15/08 05:54AM EEW
BROMOMETHANE	EPA 624	ND ug/l	1.14 ug/l	11/15/08 05:54AM EEW
CHLOROETHANE	EPA 624	ND ug/l	1.09 ug/l	11/15/08 05:54AM EEW
TRICHLOROFLUOROMETHANE	EPA 624	ND ug/l	0.980 ug/l	11/15/08 05:54AM EEW
1,1-DICHLOROETHENE	EPA 624	ND ug/l	0.750 ug/l	11/15/08 05:54AM EEW
ACETONE	EPA 624	154 ug/l	1.76 ug/l	11/15/08 05:54AM EEW
METHYLENE CHLORIDE	EPA 624	1.70 ug/l	0.690 ug/l	11/15/08 05:54AM EEW
TRANS-1,2-DICHLOROETHENE	EPA 624	ND ug/l	0.450 ug/l	11/15/08 05:54AM EEW
1,1-DICHLOROETHANE	EPA 624	ND ug/l	0.480 ug/l	11/15/08 05:54AM EEW
CARBON TETRACHLORIDE	EPA 624	ND ug/l	0.720 ug/l	11/15/08 05:54AM EEW
CHLOROFORM	EPA 624	40.5 ug/l	0.560 ug/l	11/15/08 05:54AM EEW
1,1,1-TRICHLOROETHANE	EPA 624	ND ug/l	0.520 ug/l	11/15/08 05:54AM EEW
BENZENE	EPA 624	ND ug/l	0.610 ug/l	11/15/08 05:54AM EEW
1,2-DICHLOROETHANE	EPA 624	ND ug/l	0.490 ug/l	11/15/08 05:54AM EEW
TRICHLOROETHENE	EPA 624	ND ug/l	0.660 ug/l	11/15/08 05:54AM EEW
1,2-DICHLOROPROPANE	EPA 624	ND ug/l	0.520 ug/l	11/15/08 05:54AM EEW
BROMODICHLOROMETHANE	EPA 624	4.23 ug/l	0.520 ug/l	11/15/08 05:54AM EEW
TOLUENE	EPA 624	ND ug/l	0.540 ug/l	11/15/08 05:54AM EEW
TRANS-1,3-DICHLOROPROPENE	EPA 624	ND ug/l	0.510 ug/l	11/15/08 05:54AM EEW
CIS-1,3-DICHLOROPROPENE	EPA 624	ND ug/l	0.450 ug/l	11/15/08 05:54AM EEW
1,1,2-TRICHLOROETHANE	EPA 624	ND ug/l	0.370 ug/l	11/15/08 05:54AM EEW

Thomas J. Hines
Thomas J. Hines, President

QC Laboratories

Analytical Report



Account No: W05307, COMPLETE ANALYSIS 1 WK TAT PHILLY QA
 Project No: W05307, COMPLETE ANALYSIS 1 WK TAT PHILLY QA

P.O. No:
 PWSID No:

Inv. No:

Sample Number L2826820-2
 Sample Description 813843.2 GRAB

Samp. Date/Time/Temp
 11/11/08 11:32am NA F

Sampled by
 Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
2-CHLOROETHYL VINYL ETHER	EPA 624	ND ug/l	0.620 ug/l	11/15/08 05:54AM EEW
DIBROMOCHLOROMETHANE	EPA 624	1.67 ug/l	0.460 ug/l	11/15/08 05:54AM EEW
TETRACHLOROETHENE	EPA 624	ND ug/l	0.540 ug/l	11/15/08 05:54AM EEW
CHLOROBENZENE	EPA 624	ND ug/l	0.670 ug/l	11/15/08 05:54AM EEW
ETHYL BENZENE	EPA 624	ND ug/l	0.530 ug/l	11/15/08 05:54AM EEW
BROMOFORM	EPA 624	ND ug/l	0.450 ug/l	11/15/08 05:54AM EEW
1,1,2,2-TETRACHLOROETHANE	EPA 624	ND ug/l	0.610 ug/l	11/15/08 05:54AM EEW
1,3-DICHLOROBENZENE	EPA 624	ND ug/l	0.480 ug/l	11/15/08 05:54AM EEW
1,4-DICHLOROBENZENE	EPA 624	ND ug/l	0.590 ug/l	11/15/08 05:54AM EEW
1,2-DICHLOROBENZENE	EPA 624	ND ug/l	0.550 ug/l	11/15/08 05:54AM EEW

- A result of "ND" indicates the concentration of the analyte tested was either not detected or below the RLs.
 - Definitions: ND=not detected; NEG=negative; POS=positive; COL=colonies; RLs=laboratory reporting limits; L/A=laboratory accident; TNTC=too numerous to count
 - A result marked with "DRY" indicates that the result was calculated and reported on a dry weight basis.
 - All analysis, except field tests are conducted in Southampton, PA unless otherwise identified.
 - The test "pH lab" is analyzed upon receipt at the laboratory, the result will not be suitable for regulatory purposes.
 - Actual times of analysis for parameters reported <24 hrs are available upon request. All testing is completed within the required holding time unless otherwise noted.
 - QC NELAP ID's: PA 09-00131, NJ PA166, FL E87954, NY 11223, CT PH-0768, DE PA-018, KY 90228, MD 206, EPA PA00018. Bioassay: PA 09-03574, NJ PA034, FL E87953, KS E10373, SC 89020001.
 - QC STATE ID's: Wind Gap, NJ PA001, PA 48-01334; E RUTHERFORD NJ02015; Vineland NJ06005; Reading PA 06-03543.
 - All samples are collected as "grab" samples unless otherwise identified.
 - MCL= is the EPA recommended "maximum contaminant level" for a parameter. PLs=customer specific permit limits.
 Regulatory authorities are assessing substantial fines for testing omissions. Please track your sample collections and results on a weekly, monthly, or quarterly basis to ensure compliance. QC's internet program 'LIVE ACCESS' will provide you with real-time access to collection dates and results. Please contact Customer Service for further information on acquiring LIVE ACCESS.

Thomas J. Hines
 Thomas J. Hines, President



December 17, 2008

Mr. Andy Caltagirone
Manager of Industrial & Pollution Control
Passaic Valley Sewerage Commissioners
600 Wilson Ave.
Newark, NJ 07105

Dear Mr. Caltagirone:

Enclosed are MR-2 and MR-1 periodic compliance monitoring reports, which are due on 12/21/08 and 01/4/09, respectively.

Thank you.

Sincerely yours,

Seenu Pokar
for: Jiten Parikh
Vice President

CHAIN OF CUSTODY

COMPLETE ANALYSIS LABORATORIES, INC.

1259 ROUTE 46 BLDG. # 4
 PARSIPPANY, NJ 07054-4909
 PHONE: (973) 335-CALI
 FAX: (973) 335- 0556
 NJDEP LAB CERTIFICATION # 14964

PAGE 1 OF 1
 (Lab use only) No. 813843

DELIVERABLES: ☒ STD ☐ REDUCED ☐ FULL
 (CIRCLE ONE) OTHER (Specify) _____

CLIENT	AMNEAL PHARMACEUTICAL		
ADDRESS	209 MCLEAN BLVD.		
CITY	PATERSON		
STATE	NJ	ZIP	07054

CONTACT	Ms. Thakar	PHONE	(973) 357-0222
PROJECT	WASTEWATER		
SAMPLER	C. ALTO <i>[Signature]</i> name sign		
WITNESSED BY	name <i>Senor R. Lopez</i> 11-11-08		

LAB ID	FIELD ID	SAMPLING DATE/TIME	M	T	No	P	ANALYSIS
813843.1	AP- 1111	11/11/08 11:30	A	C	1	C	BOD, TSS
813843.1	AP- 1111	11/11/08 11:31	A	C	1	Hn, C	Cu, Zn, Pb
813843.2	AP- 1111 G	11/11/08 11:32	A	G	2	H, C	VOC*
REMARKS	* VOC TO INCLUDES: ACETONE, METHYLENE CHLORIDE						
	COMPOSITE SAMPLER WAS SET UP ON 11/10/08. SAMPLE WAS COLLECTED ON 11/11/08 @ 11:30						
	SAMPLING FREQUENCY - 30 MINUTES.						

RELINQUISHED BY		RECEIVED BY		DATE	TIME	METHOD OF RELINQUISH.	RECEIVING ORGANIZATION
NAME	SIGNATURE	NAME	SIGNATURE				
C. ALTO	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	11/11/08	16:40	<i>[Signature]</i>	LAB
TURNAROUND TIME:				PRIORITY AUTHORIZATION:			
M = MATRIX	A - AQUEOUS SL - SLUDGE	P - POTABLE WATER SO - SOLID	S - SOIL X - OTHER	O - OIL			
T = TYPE	C - COMPOSITE	G - GRAB	No. = NUMBER OF CONTAINERS				
P = PRESERVATIVE	H ₂ - H ₂ SO ₄	Hn - HNO ₃	H - HCl	N - NaOH	A - ASCORBIC ACID	C - COOL TO 4 °C	

SOP-CG-010 REV 4/96

DROP DOWN BOX

NON USE CERTIFICATION MONITORING REPORT LOCAL LIMITS

NAME: AMNEAL PHARM

MAILING ADDRESS: _____

FACILITY LOCATION: _____

CATEGORY & SUBPART _____ PERMIT # _____ OUTLET #: 27200050-1

CONTACT OFFICIAL: _____ TELEPHONE #: _____

I have been authorized to certify non-use for the following heavy metals:

Arsenic _____	Lead <input checked="" type="checkbox"/>	Zinc _____	SAMPLE DATE			
Cadmium _____	Mercury _____		MONTH	DAY	YEAR	
Chromium _____	Molybdenum _____		11	11	08	
Copper _____	Nickel _____					

PARAMETER		CONCENTRATION			SAMPLE TYPE
		RESULT	THRESHOLD VALUE EXCEEDED YES OR NO	UNITS	COMP/GRAB
LEAD	Sample Measurement	0.0136	n	mg/L	Comp.
	Threshold Value	0.029		1	
METHYLENE CHLORIDE	Sample Measurement	0.00170	n	mg/L	GRAB
	Threshold Value			1	
	Sample Measurement				
	Threshold Value				
	Sample Measurement				
	Threshold Value				
	Sample Measurement				
	Threshold Value				
	Sample Measurement				
	Threshold Value				
	Sample Measurement				
	Threshold Value				
	Sample Measurement				
	Threshold Value				
	Sample Measurement				
	Threshold Value				

PVSC Form MR-3 10/96